Participant Information Sheet

MEDICAL RESEARCH INSTITUTE OF NEW ZEALAND

Study title:	**Rhinothermy in the common cold**
Locality:	Ethics committee ref.:
Lead investigator:	Contact phone number:

In the screening tests, we found that you met the criteria for this common cold study. We are studying the effect of inhaling warm, humidified air when you have the common cold. Whether or not you take part in the study is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you do want to take part now, but change your mind later, you can pull out at any time.

This Participant Information Sheet will help you to decide whether or not you would like to participate in the study. It sets out the schedule of tasks and visits needed to complete the study. We will go through this information with you and answer any questions you may have. As we need to make sure that you are enrolled into the common cold study within 48 hours of developing your symptoms, you may have only a short time to review this material before you decide whether or not to proceed. Before you decide, you may want to talk about the study with other people such as family, whānau, friends, or healthcare providers. Feel free to do this.

The study is carried out by Researchers from the Medical Research Institute of New Zealand (MRINZ) with support from Fisher and Paykel Healthcare, who make the rhinothermy device and are sponsors of the study. The Lead Investigator is xxxwho can be contacted on the phone number on page one if you would like to speak with her directly.

If you agree to take part in the study, you will be asked to sign an electronic Consent Form. You will be given a copy of this document and the signed Informed Consent Form to keep.

This study has been approved by the Southern Health and Disability Ethics Committee (17/STH/174) and is registered under the title: Rhinothermy in the Common Cold (RiCC) on: http://www.ANZCTR.org.au/ACTRN12617001340325

This document is 9 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

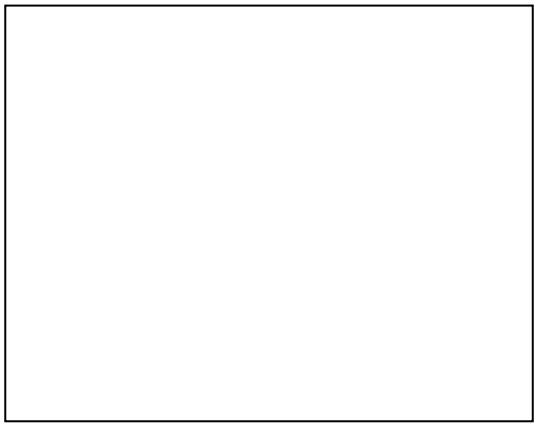
The common cold is the most frequent illness experienced by people worldwide. Many people will have experienced a cold in their lifetimes – adults on average may suffer from 2-4 colds per year. Symptoms can last for up to a week and although most people get better by themselves with no treatment, it may have a significant impact on their lives. This impact includes time off of work, which in the US alone has been estimated to cost the economy $25 billion. Finding different ways of reducing the impact of the common cold, which is

usually caused by a virus (there are many, the Human Rhinovirus being the most common), by inhaling steam has become a focus of research. It is thought that breathing in steam through the nose may kill the virus as well as reduce the symptoms and the number of days that people remain unwell. Some people will be familiar with steam therapy, like holding your face over a bowl of steaming hot water with a towel over your head.

Rhinothermy is a therapy that delivers warmed and humidified air to the nostrils and down to the lungs via nasal prongs.

The aim of the study is to show whether rhinothermy changes symptoms (length and severity) and/or reduces the number of days lost to the illness. It also aims to assess things like how often people will use rhinothermy at home and which common cold viruses people have.

A picture of a person receiving rhinothermy is shown below:



This study will compare two different regimens of rhinothermy as treatment for the common cold. These two therapies deliver warmed, humidified air through the nostrils at different settings. We believe that one of these regimens/settings is likely to be more effective than the other and this study will find out if this is true.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

This study runs for 14 days in total, starting with 5 days of treatment, and finishing with a further 9 days of recording your symptoms in a diary.

Today is Day 1:

After you sign the Informed Consent Form, we will:

- Ask you to refrain from using any cold or flu treatments for the duration of the study (14 days), and ONLY IF absolutely necessary, take paracetamol or anti-inflammatory medications (e.g. ibuprofen).
- Ask that you refrain from leaving the greater Wellington region for the first five days of the study, while you are taking one of the two possible treatments.

We will show you how to complete your online symptom diary to:

- Record any medications taken (cold and flu remedies or paracetamol etc.) each day for the next 13 days
- Record each of your common cold symptoms daily for the next 13 days

We will randomise you to one of two possible rhinothermy treatment regimens which deliver rhinothermy at different settings. The chance of you being on either treatment is 50%, like tossing a coin. We will show you how to use your rhinothermy device here today and at home for the next 4 days. You will also receive your first (Day 1) treatment here today.

Once the treatment component is completed on Day 1, you can head home, and we will advise your GP that you have been enrolled in this study.

Days 2, 3 and 4: take the randomised treatment and fill in the online diary.

Day 5: this is the final day of treatment.

- We would like you to come in after you have taken your treatment.
- We need you to bring your rhinothermy device back to the clinic.
- We will check on your general health.
- We need you to fill in your online diary.
- We will ask you to complete a tolerability questionnaire about the device.
- The next time we will contact you will be via a phone call on Day 14.

Day 6 to Day 14: Keep filling in your online diary.

Day 14: This is the final day of the study.

- We will call you to make sure that you have completed your diary, check on your general health and arrange your reimbursement for participating in the study.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

Nostril swab: The nostril swab we need to take is not painful, but some people may find it unpleasant or uncomfortable. They require a few seconds to perform and will be taken by trained staff.

Rhinothermy Devices:
The rhinothermy devices should always be used as per the instruction manual. You will be given the appropriate user manual and training which will provide information about how to use your device. Your device will have an alarm that should sound for events such as the water level in the chamber being too low. To check that the alarm is working, we will show you how to test the alarm before you use it. If you have any concerns about using your device please do not use it and refrain from using it again until you have been able to contact the study investigator and discuss your concerns.

We have found an earlier version of the rhinothermy device to be well tolerated. A small number of participants reported a mild headache, which resolved soon after they stopped using the device. Some people find the feeling of warm, humidified air uncomfortable. There have also been a very small number of cases reported where the device's alarm function did not work but no harm was caused because of this. You are able to stop using your rhinothermy device at any stage if you are concerned.

Some people get a runny nose or a blocked nose when using the device. This goes away when you stop using the device. There is also a small risk of damage to the skin around the nose and lips or getting a nosebleed while using the device. This is rare and more likely to

happen when the device is used for a longer period of time. The device use can be paused or stopped at any time during the study visit if any of these problems happen.
The rhinothermy devices contain a plate that heats up and warms water in a chamber. Care must be taken when you are inserting or removing the chamber immediately after use as the heater plate will still be hot. The risks of using the electrically powered rhinothermy devices to humidify the air are: electric shocks, burns and tubing melt down. To avoid cross-contamination of your cold, you should make sure you do not share the device with anyone else.

The study investigator may also stop you from continuing in the study if they decide it is not in your best interests to continue. The Sponsor or the MRINZ may stop the study if there any safety concerns.

DEVICE GEOLOCATION

As you will have already read in the Screening Participant Information Sheet, your rhinothermy device should not be taken or used outside of the area the study is being undertaken (the greater Wellington region). To enable the location of the devices to be traced, the devices have a geolocation function (similar to Google location services) which will collect location data.
For more detailed information, please refer to the Screening Participant Information Sheet.

WHO PAYS FOR THE STUDY?

The study is funded by Fisher and Paykel Healthcare. Participating in this study will not cost you anything. You will be paid $400 on Day 14 to cover any expenses associated with participating in this study.
If you complete only part of the study, only part of the $400 will be paid, the proportion will reflect how far you got through the study.

WHAT IF SOMETHING GOES WRONG?

If you are injured as a result of treatment given as part of this study, which is unlikely, you **will not** be eligible for compensation through ACC. However, compensation will be available from the study sponsor, Fisher and Paykel Healthcare, in line with industry guidelines. We can give you a copy of these guidelines if you wish. You will be able to take action through the courts should you disagree with the amount of compensation offered.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study will not affect your cover.

WHAT ARE MY RIGHTS?

Taking part in this study is entirely voluntary (your choice). You are free to withdraw from the study at any time, without having to give a reason. The staff overseeing the study may also stop you from continuing if they decide it is not in your best interests to continue.

With respect to your personal information;

- Your therapy and use of your rhinothermy device will be automatically recorded and analysed as part of the study.
- The paper-based and electronic records for this study will be held securely by MRINZ, and will only be available to research staff or to those who are auditing the study.

- Any electronically stored data may be held in New Zealand or overseas, but will be encrypted, and access will be limited only to those who have appropriate authorization.
- Your non-electronic study-related information will be labeled with a code. The link between the code and your name and address (identifying information) will only be held by the research staff.
- We will analyse all data, including yours, so that results may be published.
- If any study data is reported, published, or placed on a data repository (an electronic storing place) at the request of publishers, the data will be 'de-identified' so that individuals cannot be identified as a result of that data being seen.
- Sometimes, the Southern Health and Disability Ethics Committee or an auditor may want to make sure we (MRINZ) are running a study properly. They may require access to the information collected during this study to satisfy themselves of this.
- After the study, all data collected, both paper and electronic, will be kept in a secure location by the MRINZ for at least 10 years following study completion.

If you require one, we can provide interpreter to translate information for you.

You may have a friend, family or Whānau member to support and help you understand the risks and/or benefits of this study and any other explanation you may require.

If you have any queries or concerns regarding your rights as a participant in this study, you may wish to contact an independent health and disability advocate:

Free phone:
Free fax:
Email:

WHAT ARE MY RESPONSIBILITIES AS A STUDY PARTCIPANT?

We ask that you make your best effort to follow the study procedures.

As the rhinothermy device is still under commercial development with Fisher and Paykel Healthcare, we will be asking you to sign a confidentiality statement in the consent form in which you agree to keep any information relating to this study confidential.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

Taking part in this study is entirely voluntary (your choice). Your decision whether or not to take part will not affect your healthcare in any way or your future relationship with the hospital or your GP. If you wish to take part in the study, you are free to withdraw at any time, without having to give a reason. The doctor overseeing the study may also stop you from continuing in the study if they decide it is not in your best interests to continue.

At the end of the study we can give you a summary of the results. These results can be e-mailed or posted to you. There may be some delay between taking part in the study and receiving the results as the whole study needs to be finished before the results can be analysed.

At the end of the study or if you withdraw from the study before Day 14, we will collect all study related material from you. Unless you specifically request us not to, we will keep and analyse the data that was collected from you.

Usually, the swab that we take from the back of your nose at the Day 1 visit will be destroyed by the lab once the study results have been published.

Please note that the rhinothermy device is not yet commercially available and therefore will not be available for use following the end of the study. Once again, if you do agree to take part in the study initially and you change your mind, you can stop at any time, without having to give a reason.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Principal Investigator
Phone:
E-mail:
If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone:
Fax:
Email:

For Māori Heath support please contact Whānau Care Services:
Phone:
Email:

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone:
Email:

Informed Consent Form

MEDICAL RESEARCH INSTITUTE OF NEW ZEALAND

If you need an INTERPRETER, please tell us.

Please read the statements below, tick where there are boxes and sign at the end to indicate you consent to the following:

I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.		
I have been given sufficient time to consider whether or not to participate in this study.		
I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.		
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.		
I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.		
I consent to the research staff collecting and processing my information, including information about my health.		
If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.	Yes ☐	No ☐
I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study.	Yes ☐	No ☐
I agree to an approved auditor appointed by the New Zealand Health and Disability Ethic Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.		
I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.		

I have read the section on geolocation of the device and consent to the collection, use and storage of this location data.
I understand the compensation provisions in case of injury during the study.
I know who to contact if I have any questions about the study in general.
I understand my responsibilities as a study participant.
I wish to receive a summary of the results from the study. Yes ☐ No ☐

Declaration by participant:
I have read and agree to all of the above. I hereby consent to take part in this study.

Participant's name: _____

Signature: _____ Date: _____

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name: _____

Signature: _____ Date: _____

Participants' confidentiality statement:

I understand that the concept of this study, the device, accompanying information and anything I may learn or become aware of within this study is commercially sensitive. I know I must keep any information relating to this study confidential. I know I must not take any photographs or recordings of the device during the study. As I will be using the device at home I will make those I live with aware of these obligations also.

I understand my obligations to keep this information confidential.

Participant's name: _____

Signature: _____ Date: _____